

PATENT
674519-2045.1**REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks, amendments, and enclosures herein.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claim 38, 40-47 and 50-54 are pending. Claims 38, 45-47, 51 and 54 have been amended, and claims 39 and 52 have been cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the documents cited by the Examiner, and that these claims were and are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, the amendments to the claims as presented herein are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitations is found throughout the specification and from the originally pending claims.

II. RESPONSE TO RESTRICTION REQUIREMENT

Applicants hereby confirm the election of the claims of Group III for examination in this application. Applicant retains the right to file a divisional application directed towards the claims of Groups I and II.

The Office Action states that claim 47 is included in both Groups I and III because the language of claim 47 broadly encompasses multiple inventions. Applicants disagree. *Respectfully*

Claim 47 is directed towards a dough improving composition comprising a polypeptide wherein said polypeptide is capable of hydrolyzing glycolipids that are present in a flour to the corresponding galactosyl monoglycerides, wherein said polypeptide is capable of hydrolyzing at least 10% of galactosyl diglycerides present in a flour dough to monoglycerides, and at least one further conventional dough additive component.

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The Office Action alleges that the term "conventional dough additive component" may be construed to include water, which would render the claim of sufficient breadth to be included in both Groups I and III. Applicants respectfully disagree with this assertion and respectfully submit that the term "conventional dough additive component" excludes water on its face.

Specifically, the specification refers to water as a "dough ingredient", not a "dough additive component." The Examiner's attention is specifically drawn to page 6, line 29 to page 7, line 11 of the specification, wherein the first paragraph describes the process of making a bakery product dough and the required ingredients therein:

It is one objective of the invention to provide improved bakery products. In accordance with the invention, *a bakery product dough including a bread dough is prepared by mixing flour with water*, a leavening agent such as yeast or a conventional chemical leavening agent, and an effective amount of glycerol oxidase under dough forming conditions. It is, however, within the scope of the invention that *further components* can be added to the dough mixture. (Emphasis added).

The above paragraph clearly sets forth that water is an *essential ingredient* in preparing a bakery dough, such that it is not considered a "dough *additive* component." Rather, one of skill in the art would recognize that a "dough *additive* component" referred to those components which may be added to the dough, but which is not required to be present in order to form such a dough.

To this end, the Examiner's attention is respectfully drawn to page 7, lines 29-36 of the specification, wherein the paragraph reads in part, "[t]he glycerol oxidase can be added together with *any dough ingredient including the water* or dough ingredient mixture or with any additive or additive mixture." Emphasis added.

Here, the difference between dough ingredients and dough additives is clearly specified, with water considered as a *dough ingredient*, not a dough additive. Therefore, claim 47 clearly refers to a dough improving composition comprising a polypeptide wherein said polypeptide is capable of hydrolyzing glycolipids that are present in a flour to the corresponding galactosyl monoglycerides, wherein said polypeptide is capable of hydrolyzing at least 10% of galactosyl diglycerides present in a flour dough to monoglycerides, and at least one further conventional dough additive component, wherein water is not a possible dough additive component.

Furthermore, the Office Action alleges that the lipase enzyme requires water to be present, as it is a hydrolase-type enzyme. It is respectfully submitted that this is an incorrect interpretation of claim 47. Specifically, the claim relates to a dough improving composition, not

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to a dough itself. The dough improving composition comprises a polypeptide wherein said polypeptide is *capable* of hydrolyzing glycolipids. The claim does not read that the polypeptide *does* hydrolyze glycolipids *in the dough improving composition*. Rather, the dough improving composition, comprising the polypeptide that is capable of hydrolyzing glycolipids and at least one further conventional dough additive ingredient, would itself be a dough ingredient. Hence, the dough improving composition would be mixed with the necessary dough ingredients, including *water*, which would then form the dough. In other words, the water is not present in the dough improving composition; rather, the dough improving composition serves as a dough ingredient to which is mixed other required ingredients, including water, which would then allow the lipase enzyme to hydrolyze the glycolipids.

Consequently, one of skill in the art would recognize that water is a dough ingredient, and is not an additive component, such that claim 47 is correctly placed in Group III and only in Group III. Therefore, examination of the claims of Group III, including claim 47, is respectfully requested.

III. THE OBJECTIONS TO THE SPECIFICATION ARE OVERCOME

The specification was objected to due to the presence of a PCT official form for the Identification of Deposit of Microorganisms on page 65 of the specification. The objection is respectfully traversed.

The amendments to the specification herewith render the objection moot. Applicants have considered the cautionary statements relating to new matter in the Office Action, however it has been found that the material contained on the deleted page is also present in the specification on page 37, first paragraph, such that the deletion of page 65 does not raise any issue of new matter.

Consequently, reconsideration and withdrawal of the objection to the specification is respectfully requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claim 47 is rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the art that Applicants had possession of the claimed invention at the time of filing. The rejection is respectfully traversed.

The amendments to the claims herein have removed the phrase "wherein the dough component is an ingredient other than water." Thus, the claims is directed towards a dough improving composition comprising a polypeptide wherein said polypeptide is capable of hydrolyzing glycolipids that are present in a flour to the corresponding galactosyl monoglycerides, wherein said polypeptide is capable of hydrolyzing at least 10% of galactosyl diglycerides present in a flour dough to monoglycerides, and at least one further conventional dough additive component.

As described above, one of skill in the art would recognize that water cannot be considered a dough additive component. Instead, water is considered a required ingredient. Therefore, a recitation stating that the "dough component" is not water is not required as this is the meaning with which one of skill in the art would interpret the claim.

Consequently, reconsideration and withdrawal of the Section 112, first paragraph, rejection is respectfully requested.

Claims 38-39, 45-47 and 50-54 were also rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the claimed invention. The rejection is respectfully traversed.

Specifically, the Office Action requests correction of the terms "hydrolysing" and "hydrolizes" to conform with U.S. spelling conventions. The amendments to the claims herewith have corrected the spelling of these terms, such that the rejection is rendered moot.

The Office Action also rejects the use of the term "normally" in claim 38 and 45-47 as an allegedly relative term which renders the claims indefinite. The amendments to the claims herewith have removed the term, such that the rejection is rendered moot.

Claims 38 and 45 were also rejected due to the recitation of the terms "improved" and "reduced", which allegedly render the claims indefinite. Claims 38 and 45 have been amended herein to include reference to a base standard, as used in claim 40. Therefore, the rejection has been rendered moot.

Claims 50 and 43 were rejected due to misspellings which allegedly rendered the claims indefinite. The amendments herewith provide appropriate correction such that the rejection is moot.

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Claim 39 was rejected as allegedly being indefinite for including the phrase "wherein the dough does not contain added lipids." The amendments herein cancel claim 39 without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Consequently the rejection is moot.

In view of the amendments herein and the remarks above, reconsideration and withdrawal of the Section 112 rejections is respectfully requested.

V. THE ART REJECTIONS ARE OVERCOME

Claims 38-42, 44-47 and 50-54 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by "*Direct*, A Newsletter from Danisco Ingredients", September 1996.

Claims 40-43 and 47 are also rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Direct* in view of Olesen *et al.* (WO 94/04035). The rejections are traversed and will be addressed together.

The Office Action states that the *Direct* reference discloses a line of bakery lipase enzymes where the enzyme acts on flour lipids to produce a more stable dough system, which includes providing a finer and more uniform crumb structure. It is further alleged that "absent any clear and convincing evidence and/or arguments to the contrary, the enzyme would inherently possess the instantly-claimed properties for the ability to hydrolyze triglycerides, glycolipids and phospholipids." Office Action at 6.

It is respectfully submitted that the enzymes of the *Direct* reference, GRINDAMYL EXEL and specifically GRINDAMYL EXEL 26, have no activity towards glycolipids or phospholipids. To this end, the Examiner's attention is respectfully drawn to the accompanying Declaration of Jørn Borch Sørensen, an inventor of the present application.

The Declaration provides evidence relating to the activity of GRINDAMYL EXEL 16, which comprises the same lipase as in GRINDAMYL EXEL 26. Therefore, any findings relating to the activity of GRINDAMYL EXEL 16 also apply to GRINDAMYL EXEL 26.

As shown in Figure 1 of the declaration, which present HPLC traces for several compounds in the absence (top panel) or presence (bottom panel) of GRINDAMYL EXEL 16. It is respectfully submitted that the levels of digalactosyl diglyceride (DGDG – a glycolipid) and phosphatidyl choline (PC – a phospholipid) remain the same in both the presence and absence of GRINDAMYL EXEL 16. This is contrary to the results one would obtain from an enzyme that

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has activity towards glycolipids and phospholipids, where it would be expected that the initial amounts of phospholipids and glycolipids would be reduced after exposure to the enzyme.

Furthermore, as evidenced by the HPLC traces, the amount present of each of the end-products of hydrolysis on DGDG and PC (digalactosyl monoglyceride (DGMG) and lysophosphatidyl choline (LPC), respectively) are not increased after exposure to the enzyme.

Therefore, as evidenced by the experiments set forth in the accompanying Declaration, GRINDAMYL EXEL, and specifically GRINDAMYL EXEL 26, has no activity towards glycolipids or phospholipids; as such, the *Direct* reference does not teach, anticipate, or render obvious the present invention.

Consequently, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

As to the rejection under 35 U.S.C. §103(a), it is respectfully submitted that as shown above, the GRINDAMYL EXEL 26, the lipase discussed in the *Direct* reference, does not have activity towards glycolipids or phospholipids. Consequently, the Olesen reference, which refers only to E.C. 3.1.1.3 enzymes (which hydrolyze triglycerides) does not correct the deficiencies of the *Direct* reference.

Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

VII. THE DOUBLE PATENTING REJECTION IS OVERCOME

Claims 38-46, 50-54 and 47 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-10 of copending Application No. 09/727,852. Claims 38-46, 50-54 and 47 were also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-10 of copending Application No. 09/727,253. The rejection is respectfully traversed.

It is noted that the double patenting rejection is merely provisional such that the Examiner can, pursuant to MPEP 804, drop the rejection in this case, and allow this case, with the issue of alleged double patenting to be revisited in USSN 09/727,852 and 09/727,253, and if such a rejection is appropriate in those cases, in view of the language of the claims pending in those applications, and the claims allowed in this application, the Examiner can then make the

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double patenting rejection in USSN 09/727,852 and/or 09/727,253, and the rejections therein would no longer be "provisional". Simply, as to the instant application, no Terminal Disclaimer is necessary.

Thus, reconsideration and withdrawal of the double patenting rejections as to USSN 09/727,852 and 09/727,253, in accordance with MPEP 804, is respectfully requested.

CONCLUSION

In light of the amendments, remarks and enclosures herein, the application is now in condition for allowance. Consideration and entry of this paper, favorable reconsideration of the application, reconsideration and withdrawal of the objections and rejections, and prompt issuance of a Notice of Allowance are respectfully requested.

Respectfully submitted,
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